

## STANDARD OPERATING PROCEDURE

DTM-SOP-5118

New: 09/2004

Date in Service: 10/2004

Date Removed from Service: \_\_\_\_\_

**Procedure Title:** CRIS Ordering Overview and Instructions

**Author:** Michael McGann, MT (ASCP)

**Approved by:**

**Date:**

\_\_\_\_\_  
Elizabeth Read, MD Medical Director, CPS

\_\_\_\_\_  
Charles S Carter, BS Technical Director, CPS

\_\_\_\_\_  
Jo L Procter, MEd, MT (ASCP) SBB Supervisor, CPS

### Annual Review:

_____ Reviewer	_____ Date	_____ Medical Director	_____ Date
-------------------	---------------	---------------------------	---------------

_____ Reviewer	_____ Date	_____ Medical Director	_____ Date
-------------------	---------------	---------------------------	---------------

_____ Reviewer	_____ Date	_____ Medical Director	_____ Date
-------------------	---------------	---------------------------	---------------

_____ Reviewer	_____ Date	_____ Medical Director	_____ Date
-------------------	---------------	---------------------------	---------------

_____ Reviewer	_____ Date	_____ Medical Director	_____ Date
-------------------	---------------	---------------------------	---------------

_____ Reviewer	_____ Date	_____ Medical Director	_____ Date
-------------------	---------------	---------------------------	---------------

## **CRIS Ordering Overview and Instructions**

### **PRINCIPLE OR PURPOSE**

CRIS (Clinical Research Information System) is a medical laboratory information system (LIS) that supports patient care, research and management at the Warren Grant Magnuson Clinical Center and the Mark O. Hatfield Research Center. The system consists of two distinct integrated information cores - Clinical Data Repository and the Clinical Data Warehouse.

- The Clinical Data Repository is the hub of all patient and operational related interactions. Within its operation it stores patient demographics, lab results, pharmacy orders, the hospital service formulary, information from referring physicians, physician notes, links to patient images in the radiology imaging system and multidisciplinary documentation of care.
- The Clinical Data Warehouse will centralize historical patient data for retrieval and analysis. The Data Warehouse ancillary system will focus on tracking information in support of safety and organizational efficiency initiatives.

Since the Cell Processing Section (CPS) is a service based operation and plays an integral role within the Clinical Center, it is important for those who use CPS services have a guide to properly navigate the CRIS system regarding requests that pertain to CPS operations.

### **POLICY**

Cell Processing Section (CPS) adheres to regulations/standards and guidelines stipulated by the Food and Drug Administration (FDA); American Association of Blood Banks (AABB); Health and Human Services (HHS); Centers for Medicare and Medicaid Services Clinical Laboratory Improvement Amendments of 1988 guidelines.

### **SCOPE**

All requests for CPS services must be submitted through CRIS. The core of CPS services is handled within several operations. These operations are detailed within this SOP as working instructions. The working instructions will reflect what is required to initiate either an order or service request pertaining to CPS operations. Each Working Instruction will have a "Scope" assigned to it and will detail its use on how to complete a request.

### **RESPONSIBILITIES**

Clinical center staff members who work in conjunction with CPS services and/or operations are responsible for proper order/request entry using the CRIS system.

**PROCEDURAL NOTES:** Work instructions within this SOP are a guide for nursing/physician staff members on the listed tasks and do not entail all aspects of using the CRIS system on the ward/clinic or in CPS.

## **LISTING OF WORKING INSTRUCTIONS**

- 5118-1 Request CPS Processing of Clinical Product
- 5118-2 Request CPS Processing of Product for Research Use only  
(Exception: Protocol 99-CC-0168, Dr.Child's Elutriation)
- 5118-3 Ordering Pre CD34 Test Independent of Apheresis Procedure
- 5118-4 Ordering CPS Product for Infusion through the Human Cell/Tissue Component Order Set
- 5118-5 Further Manufacturing Request (Not available until March 2005)
- 5118-6 Processing for Non-CRIS Registered Recipient (Not available until March 2005)
- 5118-7 Access/Viewing CRIS Order
- 5118-8 Generating Admission Labels
- 5118-9 Completing/Canceling CRIS Order

## **REFERENCE:**

CRIS (Clinical Research Information System) Fact Sheet  
<http://cris.cc.nih.gov/public/project.html>

## Document History

<u>Date</u>	<u>Additions/Revisions/Deletions:</u>
09/2004	New Procedure

## INSTRUCTION # 5118-1 Request CPS Processing of Clinical Product via Human Cell/Tissue Processing Order

### 1. SCOPE:

Cellular therapy products, intended for human use, to be processed in the Cell Processing Section of the Department of Transfusion Medicine must be requested through CRIS via the **Human Cell/Tissue Processing Order**. The CRIS order is required even when there is a concurrent paper request form. Since this order must be submitted under the recipient, the recipient must be registered in CRIS. Each order is to request processing on a single product on a given day. If a protocol requires processing of more than one product on more than one day, a separate order must be submitted for each product to be processed on a given day.

### 2. PROCEDURE:

#### 2.1 Ordering from an Individual Order Request

- 1) Select the assigned patient/recipient from the **Patient List Display**. Click on **Enter Order** icon.
- 2) Under “Requested By” select **Other** to designate principle investigator (PI) of protocol. Type in PI’s last name and select **Written** as the “Source”.
- 3) Under “Start of Browse” select **Transfusion Medicine** → select **Human Cell/Tissue Products** → scroll to **Human Cell/Tissue Processing Order**. Click **Add**.
- 4) Complete **DTM Human Cell/Tissue Processing Order Request** as follows (highlighted fields require entry):

**Priority-** Routine

**Reason for Stat or Priority Precedence** – No Entry

**Requested Date-** Date Product to be Processed

**Note:** More than one processing date requires an order for each date.

**Donation Type-** Enter Donation Type

**Note:** this is the type of donation for this recipient.

Donation Types Currently in Use:

**Autologous** – product for which the donor is the recipient

**Directed (Allogeneic)** – product from a family related donor

**Human Cell or Tissue Type**- Select Product from Drop List

**Note:** If the product type is in question or does not appear on the list of available product types, contact CPS Scheduling Coordinator for assistance. Cord Blood, Human Pancreatic Islet Cells and Monocytes are for CPS use only.

**Lymphocytes – Manipulated:** lymphocyte products from which donor lymphocyte aliquots for donor lymphocyte infusion (DLI) are manufactured

**Marrow:** bone marrow

**Mononuclear Cells:** mononuclear cell products to be further processed (i.e., elutriation)

**Peripheral Blood Stem Cells**

Donor Information (note: for autologous donor, provide information even if recipient = donor):

**Donor Last Name**- Donor's Last Name

**Donor First Name**- Donor's First Name

**Donor MRN**- Donor's Medical Record Number (MRN)

**Donor Date of Birth**- Donor's Date of Birth

**Cryopreserve the Donation**- Select Yes or No.

**Note:** If product is to be collected and given as a fresh infusion (no cryopreservation), a Human Cell/Tissue Component Order set request will be submitted by a CPS staff member for PI.

**Special Instructions** – Required by CPS

- 1) **Protocol number** which will be used as reference protocol for processing instructions

**Note:** Protocol number appearing in CRIS header on requisition may not be accurate and will not be used by CPS staff.

- 2) **Contact person & number**

**Note:** Space allotted will limit free text entry to approximately 150 characters.

The screenshot shows a software window titled "DTM\_Human Cell /Tissue Processing Order - LAB RESULTS TEST, NONAME". The form contains the following fields and callouts:

- Order:** Human Cell/Tissue Processing Order. Callout: "Principle investigator's name appears here".
- Requested By:** Khuu, Hanh M.
- Messages:** (Empty text area)
- Ordering Information:**
  - ☐ Conditional Order. Callout: "Types Currently in Use: Autologous = product for which the donor is the recipient; Directed (Allogeneic) = product from a family related donor".
  - ★ Requested Date:** 9 /27/2004
  - ★ Donation Type:** Directed (Allogeneic)
  - ★ Human Cell or Tissue Type:** Peripheral Blood Stem Cells. Callout: "Lymphocytes – Manipulated = lymphocyte products from which donor lymphocyte aliquots for donor lymphocyte infusion (DLI) are manufactured; Marrow = bone marrow; Mononuclear Cells = mononuclear cell products to undergo further processing (i.e., elutriation); Peripheral Blood Stem Cells".
  - ★ Donor LAST Name:** Smith
  - ★ Donor FIRST Name:** John
  - ★ Donor MRN:** 00-00-00-0
  - ★ Donor Date of Birth:** 7 / 1 /1956
  - ★ Cryopreserve the Donation:** 01 - Yes
  - Special Instructions:** Protocol 99-X-9999. Contact John Doe 104-XXXX. Callout: "Protocol number; Contact person & number".

Buttons at the bottom: OK, Cancel, Item Info, Help.

5) Review and click **OK** if complete. Click **Submit**, if order is ready for submission.

**Note:** If you need to review order fields again, select order and EDIT.

6) After order is submitted click on **Orders** tab. The Clinical Manager will appear with appropriate orders listed under **Transfusion Medicine** with a **Pending Collection** status.

7) Order entry for this CPS order is now complete.

### 3. REFERENCES:

CRIS Practice Exercise Workbook, Non-Prescriber Order Entry, NIH, 2004.

## INSTRUCTION # 5118-2

### Request CPS Processing of Product for Research Use Only via the Research Human Cell/Tissue Processing Service

(Exception: Elutriation of products collected on 99-C-0168)

#### 1. SCOPE:

Cellular therapy products, for research use only, to be processed in the Cell Processing Section of the Department of Transfusion Medicine must be requested through CRIS via the **Research Human Cell/Tissue Processing Service**. The CRIS order is required even when there is a concurrent paper request form. Each order is to request processing on a single product on a given day. If a protocol requires processing of more than one product on more than one day, a separate order must be submitted for each product to be processed on a given day.

#### 2. PROCEDURE:

##### 2.1 Ordering from an Individual Order Request

- 1) Select assigned donor from **Patient/Donor List Display**. Click **Enter Order** icon.
- 2) Under "Requested By" select **Other** to designate principle investigator (PI) for protocol. Type in PI's last name and select **Written** as the "Source".
- 3) Under "Start of Browse" select **Transfusion Medicine** → select **Human Cell/Tissue Products** → scroll to **Research Human Cell/Tissue Processing Svc.** Click **Add**.
- 4) Complete **DTM Research Human Cell/Tissue Processing Service Request** as follows (highlighted fields require entry):

**Priority-** Routine

**Reason for Stat or Priority Precedence-** No Entry

**Requested Date-** Date Product to be Processed

**Note:** More than one processing date requires an order for each date.

**Donation Type-** Research

**Human Cell or Tissue Type-** Select Product From Drop List

**Note:** If product type is in question or does not appear on list of available product types, contact CPS Scheduling Coordinator for assistance. Cord Blood, Human Pancreatic Islet Cells and Monocytes are for CPS use only.

**Lymphocytes – Manipulated:** lymphocyte products from which donor lymphocyte aliquots for donor lymphocyte infusion (DLI) are manufactured

**Marrow:** bone marrow

**Mononuclear Cells:** mononuclear cell products to be further processed (i.e., elutriation)

**Peripheral Blood Stem Cells**



**Special Instructions** – Required by CPS

- 1) **Protocol number** which is used as reference protocol for processing instructions

**Note:** Protocol number appearing in CRIS header on requisition may not be accurate and will not be used by CPS staff.

- 2) **Contact person & number**

**Note:** Space allotted will limit free text entry to approximately 150 characters.

DTM\_Research Human Cell/Tissue Processing Service - LABCSC, PAT27

Order: Research Human Cell/Tissue Processing Svc

Requested By: Sheldon, Sherry

Messages: This order is to be used for collection of a blood product that is to be used for research

Ordering Information

☐ Conditional Order

Template Name:

★ Priority: Routine

Reason for STAT or Priority Precedence:

★ Requested Date: 7 / 9 / 2004

★ Donation Type: Research

★ Human Cell or Tissue Type: Peripheral Blood Stem Cells

Special Instructions: Any additional product manufacturing instructions

Principle investigator's name appears here

Protocol number  
Contact person & number

Most frequently used:  
**Peripheral Blood Stem Cells**  
**Lymphocytes – Manipulated:** lymphocyte products to be processed for research use only  
**Mononuclear cells:** mononuclear cell products to undergo further processing (i.e., elutriation)

OK Cancel Repeat

Windows Task Manager

- 5) Review and click **OK** if complete. Click **Submit**, if order is ready for submission.  
**Note:** If you need to review order fields again, select order and **EDIT**.
- 6) After order is submitted click on **Orders** tab. The Clinical Manager will appear with appropriate orders listed under **Transfusion Medicine** with a **Pending Collection** status.
- 7) Order entry for this CPS order is now complete.

### 3. REFERENCES:

CRIS Practice Exercise Workbook, Non-Prescriber Order Entry, NIH, 2004.

## INSTRUCTION # 5118-3

### Ordering Pre-CD34 Test Independent of Apheresis Procedure

#### 1. SCOPE:

This is a special laboratory test for enumeration of CD34+ cells that is performed on whole blood samples collected independent of an apheresis procedure. The test may only be ordered with prior notification to the Cell Processing Section Service Coordinator. Written or verbal orders are not acceptable because this is a laboratory test that must be requested in CRIS. Order entry is performed under the person from whom the sample is drawn (i.e., either a donor or recipient). Each order request is for a single collection. If the protocol requires that specimen collection be done over a period of more than one day, (i.e., Day 0, Day 3, and Day 5) then order entries must be submitted for each day of specimen collection.

#### 2. PROCEDURE:

##### 2.1 Ordering from an Individual Order Request

- 1) Select assigned donor or recipient from **Patient/Donor List Display**. Click on **Enter Order** icon.
- 2) Under “Requested By” select **Other** to designate principle investigator (PI) for protocol. Type in the PI’s last name and select **Written** for “Source”.
- 3) Under “Start of Browse” select **Transfusion Medicine** → select **Human Cell/Tissue Products**→ scroll to **Pre-CD34**.
- 4) Select **Pre-CD34**, click **ADD**.

Order Entry Worksheet - LAB RESULTS TEST, NONAME

Allergies: Drug: acetaminophen; Other: Needs Allergy Assessment

Requested By: ☒ Me ☐ Other: \_\_\_\_\_ Source: \_\_\_\_\_

Date: \_\_\_\_/\_\_\_\_/\_\_\_\_ Time: \_\_\_\_:\_\_\_\_:\_\_\_\_

Session  
Type: Today Outpt/Current Inpt Reason: \_\_\_\_\_

Start Of Browse: \_\_\_\_\_ Contents of /Transfusion Medicine/Human Cell/Tissue Products'

Tree View:

- Spiritual Ministry
- Transfusion Medicine
  - Apheresis/Therapeutics
  - Blood Components
  - Consults
  - Diagnostic Lab Tests
  - Human Cell/Tissue Products
  - Protocol Order Sets
  - Transfusion Reaction Reporting

Type here to enter order name

Order	Cost
Human Cell/Tissue Product Infusion	
Pre-CD34	
This test requires prior approval by the Chief of Cell Processing (301-435-4801)	
Research Human Cell/Tissue Processing Svc	
This order is to be used for collection of a blood prod that is to be used for research purposes only. Do no this order if the product is intended for human use.	

Buttons: Add... View... Item Info... Message... Edit... Delete Copy... Add Specimen...

Submit Cancel Hide Worksheet Help

- 5) **DTM Pre-CD34 Test** entry screen will appear.
- 6) Complete **DTM Pre-CD34 Order Request** as follows (highlighted fields require entry):

**Priority-** Routine, unless CPS is notified of an emergent situation

**Reason for Stat or Priority Precedence-** Comment required if order is **not** routine

**Requested Date-** Date specimen collected

**Note:** A Pre-CD34 order request is required for each specimen collected.

**Preparation/Additional Instructions-** No Entry

**Alternate Printing Note-** "Specimen collections and labeling printing will occur at the patient's registered clinic/unit location at the time the specimen is due to be drawn. If you want specimen collections and label printing to occur elsewhere, indicate location in the field below.

**Specimen Collection/Label Printing Site-** Used in conjunction with Alternate Printing Note. If specimen is not drawn at site of patient's registered clinic/unit location, please select from pick list the nearest label printing site available to obtain specimen labels.

**NOTE:** Specimens that are not labeled in accordance with Clinical Center policies are not accepted by CPS.

**Note:** Patient or donor information appears along top border with name of order.

DTM Pre-CD34 Test - LAB/CSC, PAT27

Order: Pre-CD34 Order ID: 001BHP980

Requested By: Sheldon, Sherry

Messages: This test requires prior approval by the Chief of Cell Processing (301-435-4801).

Ordering Information:

☐ Conditional Order  Template Name:

★ Priority: Routine

Reason for STAT or Priority Precedence:

★ Requested Date: 7/9/2004

Preparation/Additional Instructions: Draw specimen and submit in a lavender topped tube and send it to Transfusion Medicine tube station 3D.

Alternate Printing Note: Specimen collection and label printing will occur at the patient's registered clinic/unit location at the time the specimen is due to be drawn. If you want specimen collection and label printing to occur elsewhere, indicate location in the field below.

Specimen Collection/Label Printing Site:

Special Instructions:

OK Cancel Repeat

**Special Instructions-** Required by CPS

- 1) Protocol number
- 2) Contact person & number for reporting results

### 3) Additional sample identifiers (i.e., day 0, day 4)

**Note:** Space allotted will limit free text entry to approximately 150 characters.

DTM\_Pre-CD34 Test - LAB RESULTS TEST, NONAME

Order: Pre-CD34 Order ID: 001GLL363

Requested By: Khuu, Hanh M

Messages: This test requires prior approval by the Chief of Cell Processing (301-435-4801).

Ordering Information

☐ Conditional Order *Condition...* Template Name:

★ Priority: Routine

Reason for STAT or Priority Precedence:

★ Requested Date: 9/15/2004

Preparation/Additional Instructions: Draw specimen and submit in a lavender topped tube and send it to Transfusion Medicine tube station 3D.

Alternate Printing Note: Specimen collection and label printing will occur at the patient's registered clinic/unit location at the time the specimen is due to be drawn. If you want specimen collection and label printing to occur elsewhere, indicate location in the field below.

Specimen Collection/Label Printing Site: 02 - Apheresis (1st Floor)

Special Instructions: Protocol # 96-H-0049, H.Khuu 104-9876, GCSF Day 4

OK Cancel Repeat Item Info Help

- 7) If **DTM Pre-CD34 Order Request** is complete click **OK** button in lower left corner.
- 8) **Order Entry Worksheet** will reappear. Click **Submit**.
- 9) After order is submitted click on **Orders** in donor/recipient (patient) record.
- 10) Clinical Manager will display order under **Transfusion Medicine** with **Pending** status.
- 11) Order entry for Pre-CD34 order is now complete.

### 3. REFERENCES:

CRIS Practice Exercise Workbook, Non-Prescriber Order Entry, NIH, 2004

## INSTRUCTION # 5118-4

### Ordering CPS Product for Infusion via Human Cell/Tissue Component Order Set

#### 1. SCOPE:

CPS products intended for infusion to patients must be requested in CRIS, even if there is a concurrent paper request form. Infusions of CPS products are ordered via **Human Cell/Tissue Component Orders**. Within this order set are a LAB component order and a NURSING infusion order. The LAB order is interfaced with the clinical laboratory's ancillary computer system (SoftLab). SoftLab allows for tracking of products distributed through CPS. The NURSING infusion order provides instructions to nursing staff administering the product.

**A CPS Human Cell/Tissue Component Order is an order set that requires both a Component and an Infusion Order to be submitted.**

#### 2. PROCEDURE:

##### 2.1 Ordering from an Order Set

- 1) Select assigned patient/recipient from **Patient List Display**. Click on **Enter Order** icon.
- 2) Under "Requested By" select **Other** to designate principle investigator (PI) for protocol. Type in the PI's last name and select **Written** for "Source".
- 3) Under "Start of Browse" → select **Transfusion Medicine** → select **Human Cell/Tissue Products** select **Human Cell/Tissue Component Orders**. Click **ADD**.

Order Entry Worksheet - LAB RESULTS TEST, NONAME

Allergies: Drug: acetaminophen; Other: Needs Allergy Assessment

Requested By: ☐ Me ☐ Other: \_\_\_\_\_

Date: \_\_\_\_/\_\_\_\_/\_\_\_\_ Time: \_\_\_\_:\_\_\_\_:\_\_\_\_

Session  
Type: Today Output/Current Inpt Reason: \_\_\_\_\_

Start Of Browse: \_\_\_\_\_ Contents of 'Transfusion Medicine/Human Cell/Tissue Products'

Respiratory Care/Pulmonary Function  
Social Work  
Spiritual Ministry  
Transfusion Medicine  
Apheresis/Therapeutics  
Blood Components  
Consults  
Diagnostic Lab Tests  
**Human Cell/Tissue Products**  
Protocol Order Sets  
Transfusion Reaction Reporting

Type here to enter order name

Order	Cost
<b>Human Cell/Tissue Component Orders</b>	
Human Cell/Tissue Processing Order	
Human Cell/Tissue Product Infusion	
Pre-CD34	
This test requires prior approval by the Chief of Cell Processing (301-435-4801).	
Research Human Cell/Tissue Processing Svc	
This order is to be used for collection of a blood product that is to be used for research purposes only. Do not use this order if the product is intended for human use.	

Add... View... Item Info... Message... Edit... Delete... Copy... Add Specimen...

Submit Cancel Hide Worksheet Help

**Note:** Order Set Summary appears.

Order Set: Human Cell/Tissue Component Orders

Order Items

Components			
<input type="checkbox"/>	<input type="checkbox"/>	Cord Blood	T Routine
<input type="checkbox"/>	<input type="checkbox"/>	Human Pancreatic Islet Cells	T Routine
<input type="checkbox"/>	<input type="checkbox"/>	Leukocytes	T Routine
<input type="checkbox"/>	<input type="checkbox"/>	Lymphocytes-Manipulated	T Routine
<input type="checkbox"/>	<input type="checkbox"/>	Marrow	T Routine
<input type="checkbox"/>	<input type="checkbox"/>	Monocytes	T Routine
<input type="checkbox"/>	<input type="checkbox"/>	Mononuclear Cells	T Routine
<input type="checkbox"/>	<input type="checkbox"/>	Peripheral Blood Stem Cells	T Routine
Infusion Orders			
<input type="checkbox"/>	<input type="checkbox"/>	Human Cell/Tissue Product Infusion	T Routine

Select All Deselect All Edit... Change Date...

OK Cancel Help

- 4) Select **Component/ Product Type** for infusion. Click **EDIT**.  
**Note:** If there is a question of what product to order, contact CPS Scheduling Coordinator for verification.  
**Note:** It is possible to select more than one product type.
- 5) Complete **DTM CPS Components** (highlighted fields require entry) as follows:  
**Note:** A separate order is required for each component **type** (e.g., a PBSC infusion event with a T cell addback requires a PBSC component order and a Lymph component order). See ATTACHMENT 1 for ordering PBSC with T cell addback. To know what products are available for a recipient request a Summary of Clinical Products (DTM-FORM-5111) from the CPS Service Coordinator.

**Priority-** Routine

**Reason for Stat or Priority Precedence-** No Entry

**Requested Date-** Date of Infusion

**Product Number-** Enter Alpha Numeric Identifier

**Number of Units Requested-** Up to 6 units selected from pick list (additional unit numbers are typed in)

**Note:** One unit is defined as one aliquot for the infusion event. Each aliquot has a unique extension or no extension (e.g., PBSC A, Lymph B or PBSC)

Enter total number of “units” to be infused of the same component type, even if multiple product numbers are involved.

Example: 04KS0143 PBSC A-F = 6 units  
04KS0147 PBSC A-B = 2 units

If both products are ordered for infusion, enter 8 units.

**Special Instructions-** Required by CPS

- 1) Product number and product type and extension
- 2) Protocol number for which processing was performed
- 3) Request for additional manipulations such as T cell addback
- 4) Total CD34 dose and/or total CD3 dose to be infuse
- 5) Contact person & number for issues or concerns about the product to be in fused (i.e., dose, sterility issue or abnormal test result)

DTM CPS Components - LAB RESULTS TEST, NONAME

Order: Peripheral Blood Stem Cells Order ID: 001GKP424

Requested By: Khuu, Hanh M

Messages:

Ordering Information:

☐ Conditional Order Condition... Template Name:

★ Priority: Routine

Reason for STAT or Priority Precedence:

★ Requested Date: 9/20/2004

★ Product Number: 00000000

★ Number of Units Requested: 9

Special Instructions: Includes 04KX0165 PBSC A-E and 04KX0167 PBSC A-D. Protocol 03-C-0077. CD34 dose 6.19x10e6/kg. CD3 dose 5.98x10e8/kg.

Infusion Reminder: Nursing: Do not administer blood products until infusion orders are entered.

OK Cancel Repeat Item Info Help

Principle investigator's name appears here

Required Special Instructions:

- 1) Product number, product type and extension (e.g., 04KX0165 PBSC A-E)
- 2) Protocol number
- 3) Total CD34 dose and CD3 dose to be

6) If **DTM CPS Components** order is complete click **OK** in lower left corner.

- 7) Order Set Summary appear: select **Infusion Order**→ select **EDIT**→ **DTM Human Cell/Tissue Product Infusion** appears (highlighted areas require entry):

**Priority**- Routine

**Reason for Stat or Priority Precedence**- No Entry

**Requested Date**- Date of Infusion

**Preparation/Additional Instructions**- **No Entry** (request to delete field pending)

**Product Number**- Enter alpha numeric identifier

**Human Cell and Tissue Type**- Enter product type from drop list

**Note:** If order consists of more than one product type, enter primary product type for infusion (e.g., PBSC with T-cell addback, select PBSC only). Refer to Summary of Clinical Products (DTM-FORM-5111) for list of available components.

**Special Instructions**- No Entry

DTM\_Human Cell /Tissue Product Infusion Order - LAB RESULTS TEST, NONAME

Order: Human Cell/Tissue Product Infusion Order ID: 001GKP444

Requested By: Khuu, Hanh M

Messages:

Ordering Information:

☐ Conditional Order Condition... Template Name:

★ Priority: Routine

Reason for STAT or Priority Precedence:

★ Requested Date: 9/20/2004

Preparation/Additional Instructions: You are only allowed to request eight components on a single order. If you need more than eight, you must submit an additional order(s). Include specific cell doses, if applicable (i.e. CD3 dose 2X10E4).

★ Product Number 1: 0000000000

★ Human Cell or Tissue Type 1: Peripheral Blood Stem Cells

Product Number 2:

OK Cancel Repeat Item Info Help

- 8) After **DTM Human Cell/Tissue Product Infusion Order** is complete click the **OK** button in the lower left corner.
- 9) Order Set Summary appears. Click **OK**.
- 10) **Order Entry Worksheet** reappears. Click **Submit**.
- 11) After order is submitted, click **Orders** tab. Clinical Manager appears with appropriate orders listed under **Transfusion Medicine** with **Pending** status.
- 12) Manual order entry for CPS order set is now complete.



### **3. ATTACHMENTS**

#### **ATTACHMENT 1: PBSC with T-cell addback component order**

### **4. REFERENCES:**

CRIS Practice Exercise Workbook, Non-Prescriber Order Entry, NIH, 2004.

## ATTACHMENT 1 Component Order for PBSC with T cell Addback

**Order Entry Worksheet - LAB RESULTS TEST, NONAME**

Allergies: Drug: acetaminophen; Other: Needs Allergy Assessment

Requested By: ☐ Me ☐ Other: \_\_\_\_\_ Source: \_\_\_\_\_

Date: \_\_\_\_/\_\_\_\_/\_\_\_\_ Time: \_\_\_\_:\_\_\_\_:\_\_\_\_

Session  
Type:  Reason: \_\_\_\_\_

Start Of Browse

☐ Respiratory Care/Pulmonary Function  
☐ Social Work  
☐ Spiritual Ministry  
☐ Transfusion Medicine  
    ☐ Apheresis/Therapeutics  
    ☐ Blood Components  
    ☐ Consults  
    ☐ Diagnostic Lab Tests  
    ☒ **Human Cell/Tissue Products**  
    ☐ Protocol Order Sets  
    ☐ Transfusion Reaction Reporting

Type here to enter order name

Order	Cost
<b>Human Cell/Tissue Component Orders</b>	
<input checked="" type="checkbox"/> <b>Human Cell/Tissue Processing Order</b>	
<input checked="" type="checkbox"/> <b>Human Cell/Tissue Product Infusion</b>	
<input checked="" type="checkbox"/> <b>Pre-CD34</b>	
This test requires prior approval by the Chief of Cell Processing (301-435-4801).	
<input checked="" type="checkbox"/> <b>Research Human Cell/Tissue Processing Svc</b>	
This order is to be used for collection of a blood product that is to be used for research purposes only. Do not use this order if the product is intended for human use.	

Add...  
View...  
Item Info...  
Message...  
Edit...  
Delete  
Copy...  
Add Specimen...

Submit Cancel Hide Worksheet Help

**Order Set Summary**

Order Set:

Order Items

Components			
<input type="checkbox"/>	<input checked="" type="checkbox"/> Cord Blood	T	Routine
<input type="checkbox"/>	<input checked="" type="checkbox"/> Human Pancreatic Islet Cells	T	Routine
<input type="checkbox"/>	<input checked="" type="checkbox"/> Leukocytes	T	Routine
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> Lymphocytes-Manipulated	T	Routine
<input type="checkbox"/>	<input checked="" type="checkbox"/> Marrow	T	Routine
<input type="checkbox"/>	<input checked="" type="checkbox"/> Monocytes	T	Routine
<input type="checkbox"/>	<input checked="" type="checkbox"/> Mononuclear Cells	T	Routine
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> Peripheral Blood Stem Cells	T	Routine
Infusion Orders			
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> Human Cell/Tissue Product Infusion	T	Routine

Select All Deselect All Edit... Change Date...

OK Cancel Help

DTM CPS Components - LAB RESULTS TEST, NONAME	
Order:	Lymphocytes-Manipulated
Order ID:	001GKP459
Requested By:	Khuu, Hanh M
Messages:	
Ordering Information	
<input type="checkbox"/> Conditional Order	Condition...
Template Name:	
★ Priority:	Routine
Reason for STAT or Priority Precedence:	
★ Requested Date:	9 /13/2004
★ Product Number:	0000000000
★ Number of Units Requested:	01 Unit
Special Instructions:	04KX0183 Lymph A. Protocol 04-H-0112. T-cell addback to CD3 dose 2x10e4/kg.
Infusion Reminder:	Nursing: Do not administer blood products until infusion orders are entered.
OK Cancel Repeat Item Info Help	

DTM CPS Components - LAB RESULTS TEST, NONAME	
Order:	Peripheral Blood Stem Cells
Order ID:	001GKP476
Requested By:	Khuu, Hanh M
Messages:	
Ordering Information	
<input type="checkbox"/> Conditional Order	Condition...
Template Name:	
★ Priority:	Routine
Reason for STAT or Priority Precedence:	
★ Requested Date:	9 /13/2004
★ Product Number:	0000000000
★ Number of Units Requested:	01 Unit
Special Instructions:	04KX0183 PBSC B. Protocol 04-H-0112. CD34 dose 5.32x10e6/kg.
Infusion Reminder:	Nursing: Do not administer blood products until infusion orders are entered.
OK Cancel Repeat Item Info Help	

DTM\_Human Cell /Tissue Product Infusion Order - LAB RESULTS TEST, NONAME

Order: Human Cell/Tissue Product Infusion      Order ID: 001GKP484

Requested By: Khuu, Hanh M

Messages:

Ordering Information

☐ Conditional Order            Template Name:

★ Priority: Routine

Reason for STAT or Priority Precedence:

★ Requested Date: 9 /13/2004

Preparation/Additional Instructions: You are only allowed to request eight components on a single order. If you need more than eight, you must submit an additional order(s). Include specific cell doses, if applicable (i.e. CD3 dose  $2 \times 10^6$ ).

★ Product Number 1: 0000000

★ Human Cell or Tissue Type 1: Peripheral Blood Stem Cells

Product Number 2:

OK      Cancel      Repeat      Item Info      Help

## INSTRUCTION # 5118-7

### Access/Viewing CRIS Orders

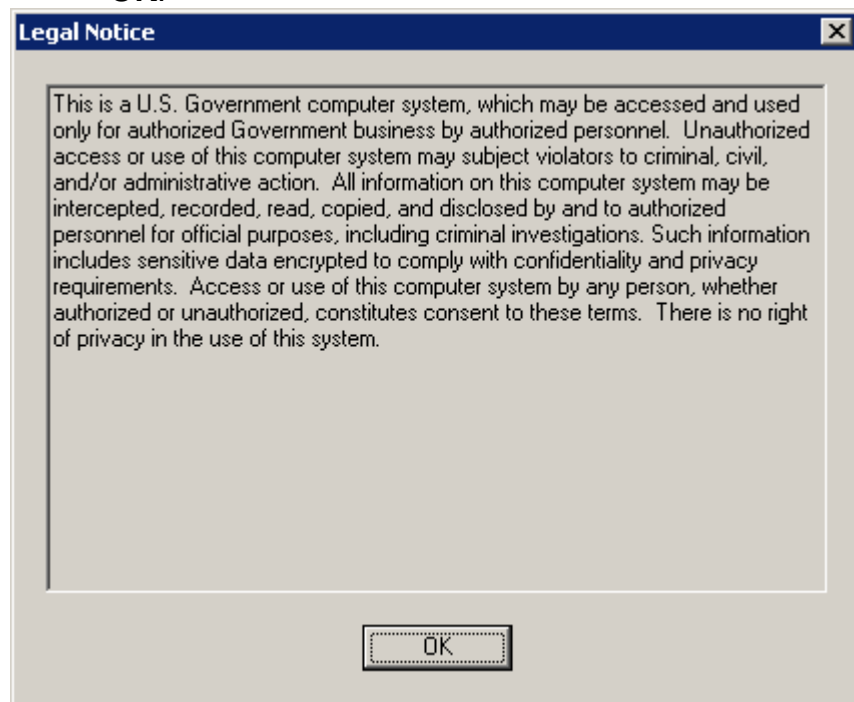
#### 1. SCOPE:

The CRIS operating system is a web based application and should be accessed to perform specified functions in the manufacture of HCT/Ps. This procedure will outline the steps to sign into CRIS, locate a patient, create a temporary list, and view orders entered for the patient of interest.

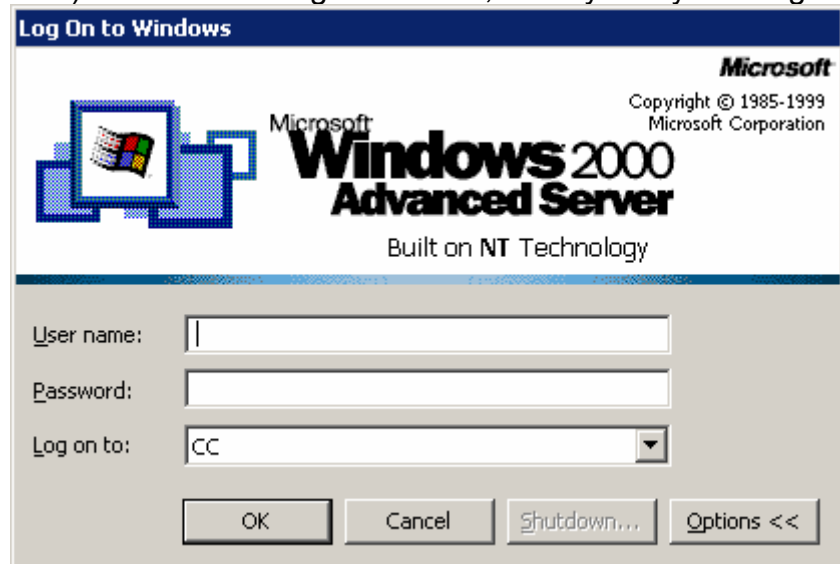
#### 2. PROCEDURE:

##### 2.1 Access to CRIS

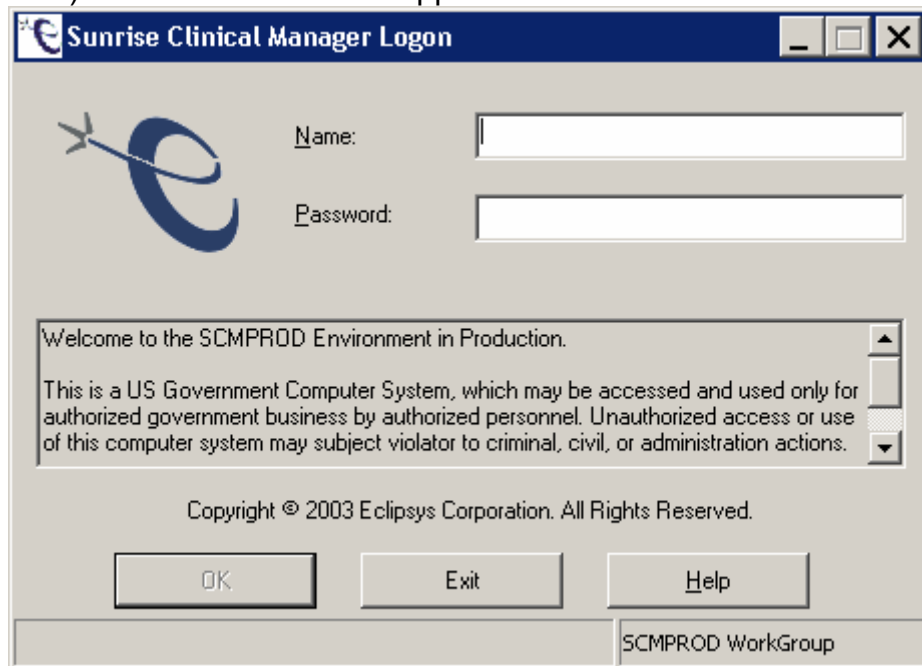
- 1) Left double click on **CRIS** icon from your local workstation to start Citrix. Click **OK**.



- 2) At Windows sign in screen, enter your system sign on user name and password.



- 3) **CRIS Client Server** appears. Enter **CRIS** user name and password. Select **OK**.



The image shows the 'Sunrise Clinical Manager Logon' window. It features a logo on the left and two input fields for 'Name' and 'Password'. Below these fields is a text box with a welcome message and a disclaimer: 'Welcome to the SCMPROD Environment in Production. This is a US Government Computer System, which may be accessed and used only for authorized government business by authorized personnel. Unauthorized access or use of this computer system may subject violator to criminal, civil, or administration actions.' At the bottom, there are three buttons: 'OK', 'Exit', and 'Help'. A status bar at the very bottom indicates 'SCMPROD WorkGroup'.

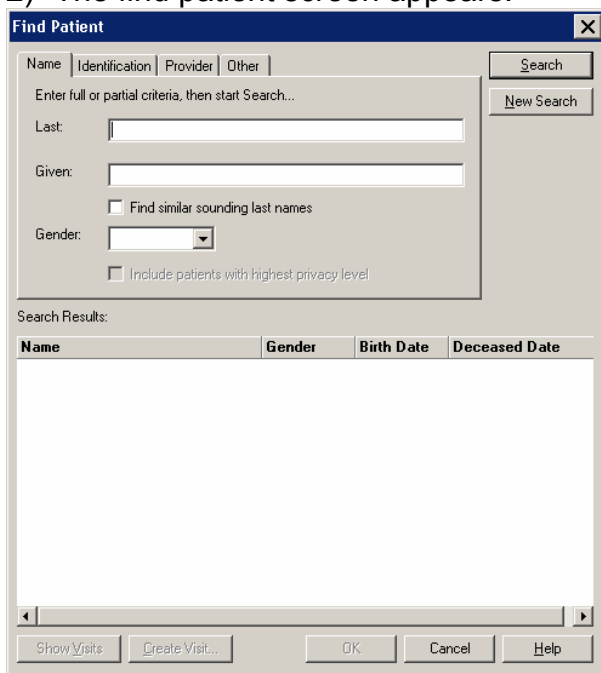
- 4) A CRIS default screen appears.

## 2.2 To locate a patient:

- 1) To locate a patient, click on **Find patient** icon.

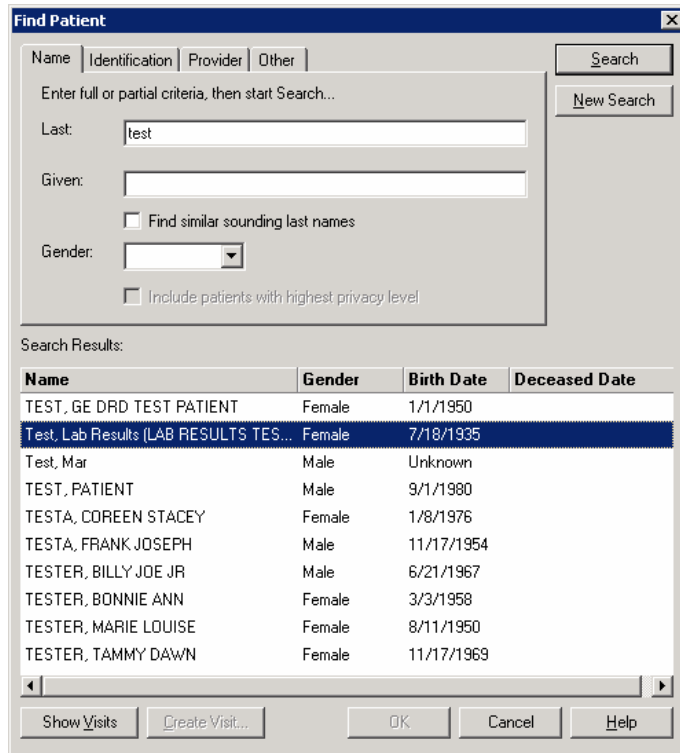


- 2) The find patient screen appears.



The image shows the 'Find Patient' search window. It has tabs for 'Name', 'Identification', 'Provider', and 'Other'. The 'Name' tab is selected. Below the tabs are input fields for 'Last' and 'Given' names, a 'Gender' dropdown menu, and two checkboxes: 'Find similar sounding last names' and 'Include patients with highest privacy level'. There are 'Search' and 'New Search' buttons. Below the search fields is a 'Search Results' section with a table header: 'Name', 'Gender', 'Birth Date', and 'Deceased Date'. The table body is currently empty. At the bottom, there are buttons for 'Show Visits', 'Create Visit...', 'OK', 'Cancel', and 'Help'.

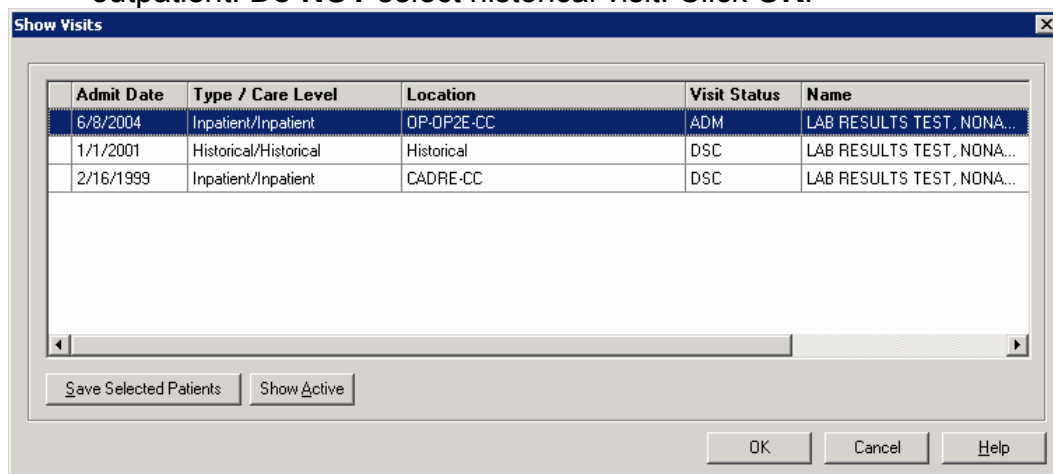
- 3) Type patient's last name, given or first name and click **Search**.
- 4) One or more patients with same last name will appear. Select patient of interest and click **Show Visits**.



The 'Find Patient' dialog box contains tabs for Name, Identification, Provider, and Other. The Name tab is active, showing a search criteria section with fields for Last, Given, and Gender, along with checkboxes for 'Find similar sounding last names' and 'Include patients with highest privacy level'. Search buttons are located on the right. Below is a 'Search Results' table with columns for Name, Gender, Birth Date, and Deceased Date. The table lists several patients, with 'Test, Lab Results (LAB RESULTS TES...' selected. At the bottom are buttons for 'Show Visits', 'Create Visit...', 'OK', 'Cancel', and 'Help'.

Name	Gender	Birth Date	Deceased Date
TEST, GE DRD TEST PATIENT	Female	1/1/1950	
<b>Test, Lab Results (LAB RESULTS TES...</b>	<b>Female</b>	<b>7/18/1935</b>	
Test, Mar	Male	Unknown	
TEST, PATIENT	Male	9/1/1980	
TESTA, COREEN STACEY	Female	1/8/1976	
TESTA, FRANK JOSEPH	Male	11/17/1954	
TESTER, BILLY JOE JR	Male	6/21/1967	
TESTER, BONNIE ANN	Female	3/3/1958	
TESTER, MARIE LOUISE	Female	8/11/1950	
TESTER, TAMMY DAWN	Female	11/17/1969	

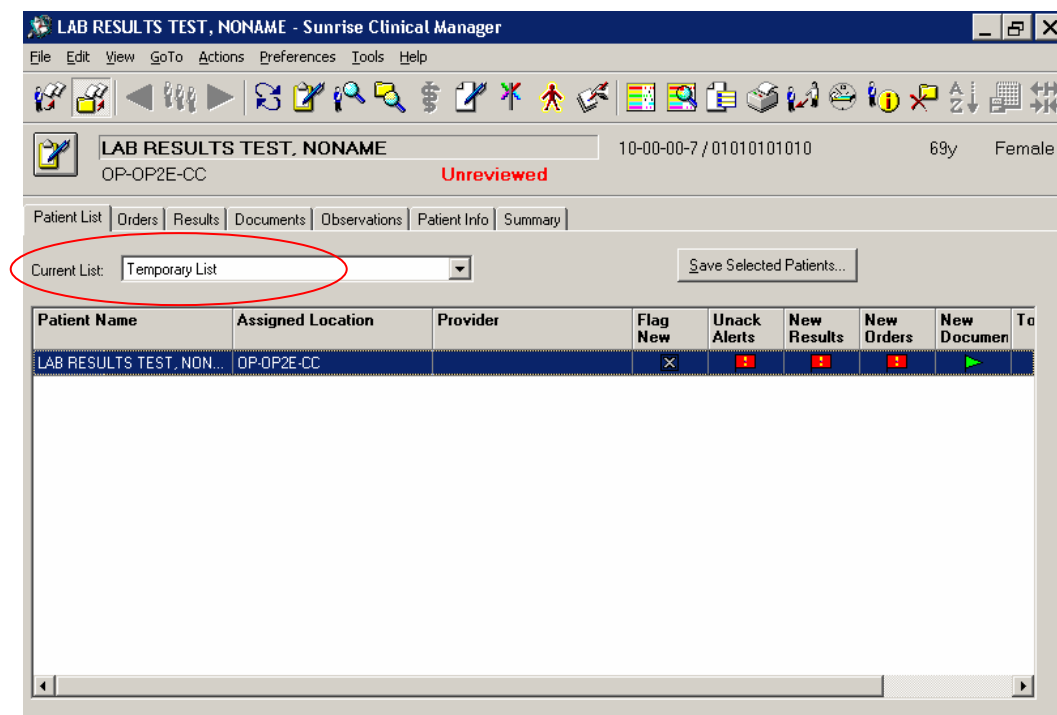
- 5) Show visits screen appears. Select visit with most recent date, either inpatient or outpatient. **Do NOT** select historical visit. Click **OK**.



The 'Show Visits' dialog box displays a table of patient visits. The table has columns for Admit Date, Type / Care Level, Location, Visit Status, and Name. Three visits are listed, with the most recent (6/8/2004) selected. Below the table are buttons for 'Save Selected Patients' and 'Show Active'. At the bottom right are 'OK', 'Cancel', and 'Help' buttons.

Admit Date	Type / Care Level	Location	Visit Status	Name
<b>6/8/2004</b>	<b>Inpatient/Inpatient</b>	<b>OP-OP2E-CC</b>	<b>ADM</b>	<b>LAB RESULTS TEST, NONA...</b>
1/1/2001	Historical/Historical	Historical	DSC	LAB RESULTS TEST, NONA...
2/16/1999	Inpatient/Inpatient	CADRE-CC	DSC	LAB RESULTS TEST, NONA...

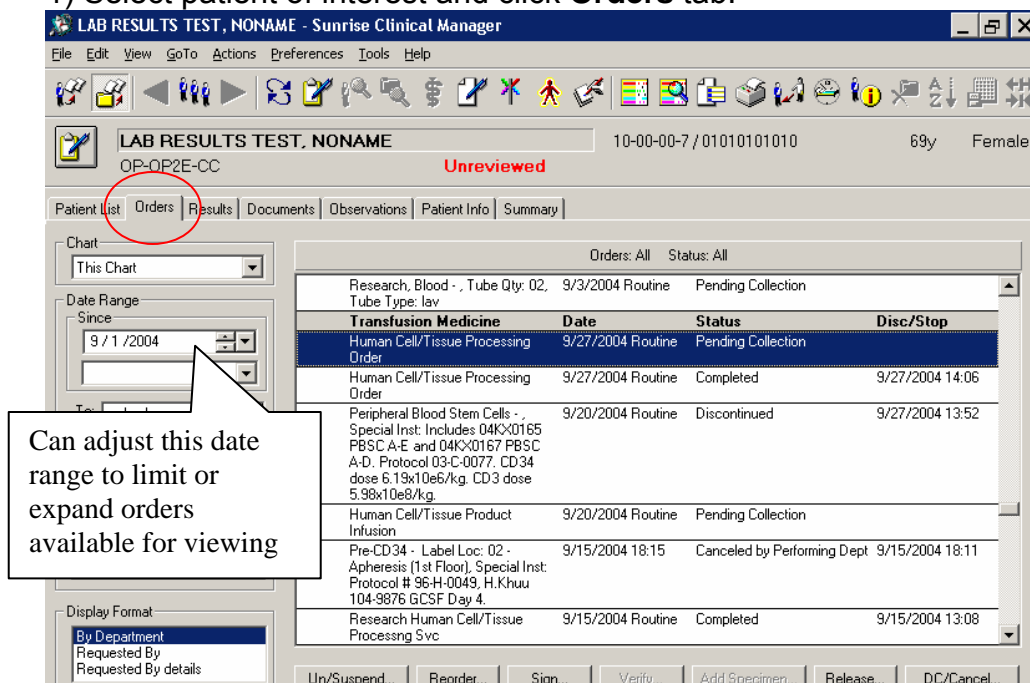
6) A temporary list of patients is generated.



**Note:** To add additional patients to temporary list, repeat steps 1-6.

## 2.3 To view orders for a patient:

1) Select patient of interest and click **Orders** tab.



2) Select order of interest by moving scroll bar up and down.



3) Left double click order of interest to view order details.

The screenshot shows a software window titled "DTM\_Human Cell/Tissue Processing Order - LAB RESULTS TEST, NONAME". The window contains the following fields and controls:

- Order:** Human Cell/Tissue Processing Order
- Order ID:** 001GQB706
- Requested By:** Khuu, Hanh M
- Ancillary ID:** (empty)
- Messages:** (empty)
- Ordering Information:**
  - ☐ Conditional Order
  - Template Name:** (empty)
- Starred Fields (Required):**
  - Requested Date:** 9 /27/2004
  - Donation Type:** Directed (Allogeneic)
  - Human Cell or Tissue Type:** Peripheral Blood Stem Cells
  - Donor LAST Name:** Smith
  - Donor FIRST Name:** John
  - Donor MRN:** 00-00-00-0
  - Donor Date of Birth:** 7 / 1 /1956
  - Cryopreserve the Donation:** 01 - Yes
- Special Instructions:** Protocol 99-X-9999. Contact John Doe 104>XXXX
- Buttons:** OK, Close, Repeat, Item Info, Help

3. REFERENCES:

CRIS User Guide, NIH, 2004.

## INSTRUCTION # 5118-8

### Generating Admission Demographic Labels

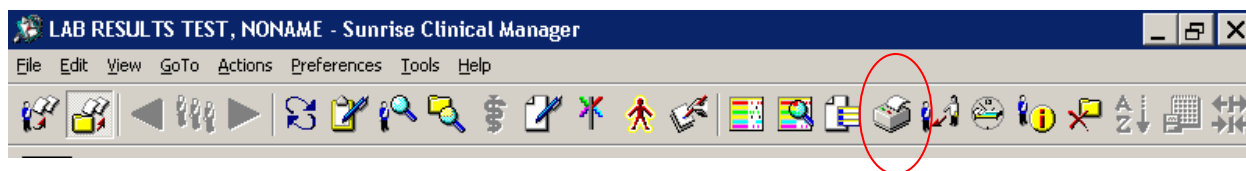
#### 1. SCOPE:

Due to numerous processing documents used within CPS daily operations, the ability to print donor and recipient demographic labels is a necessity. The labels include name, MRN (Medical Record Number), birthdate and miscellaneous demographic information such as age, race and gender. The labels generated are used for document labeling and are not a substitute for any other type of demographic label generated within CPS operations (e.g., sterility testing or micro. orders).

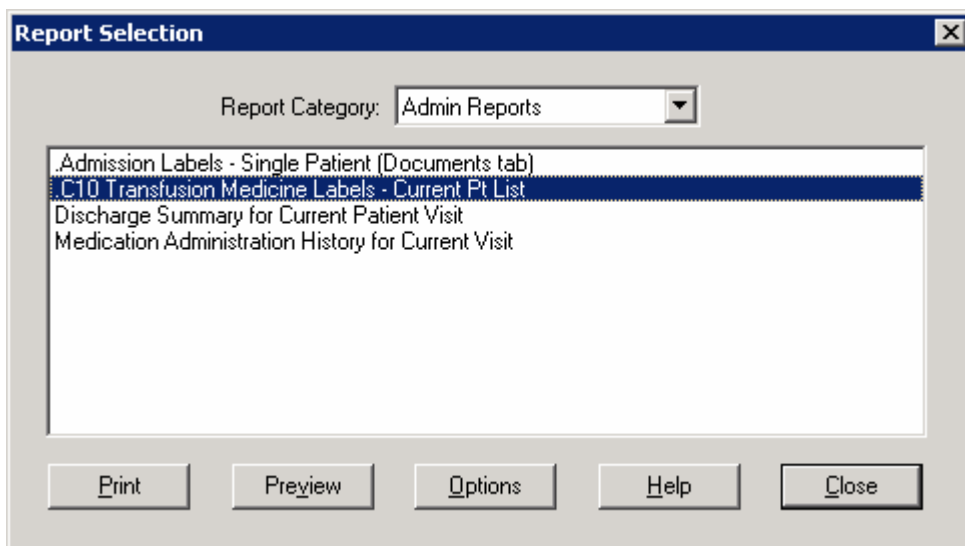
#### 2. PROCEDURE:

##### 2.1 Generating Admission Demographic Labels

- 1) Locate patient per instructions outlined in 5118-7 CRIS Access/Viewing Orders.
- 2) Click **Print Reports** icon on toolbar.



- 3) A **Report Selection** window appears. Within Report Category, select **Admin. Reports** from drop list.



- 4) Within **Admin. Reports**, select **C10 Transfusion Medicine Labels – Current Pt List** and click **Options**.

- 5) The **Report Submissions Information** screen appears and defaults to **Parameters** tab. Enter **Number of Labels** to be printed.

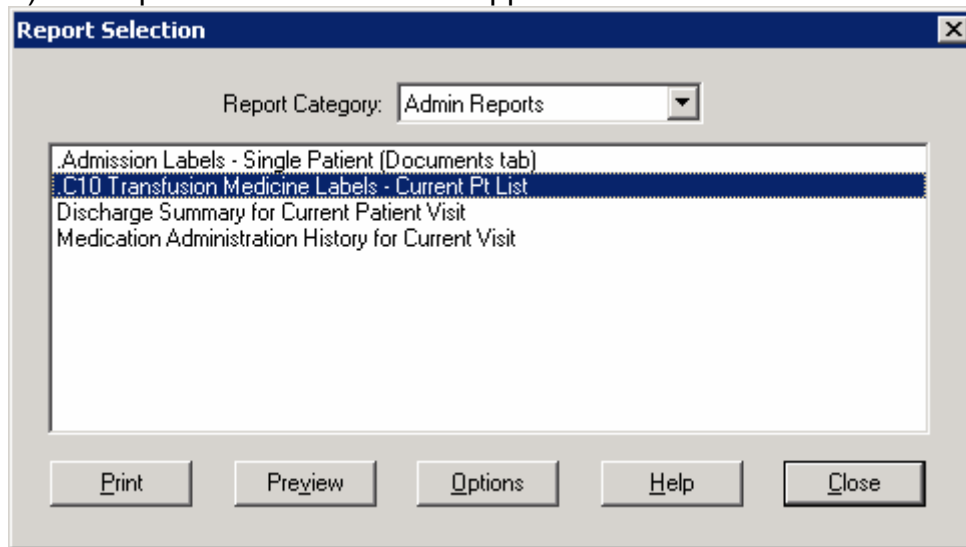
The screenshot shows the 'Report Submission Information' dialog box with the 'Parameters' tab selected. The 'Report Name' field contains 'NIH Blood Bank Labels'. The 'Instructions' field is empty. The 'Selection Criteria' section contains a 'Number of Labels\*' field with the value '20'. At the bottom are buttons for 'Print', 'Preview', 'Cancel', and 'Help'.

- 6) Click on **Distribution** tab. Click on radial button for **Physical Printer**. Enter full name of label printer \\ccxapprt1\scm-dtm-3c709L. Click **Print**.

The screenshot shows the 'Report Submission Information' dialog box with the 'Distribution' tab selected. The 'Print Policy' section has five radio buttons: 'Patient Location', 'Assigned' (selected), 'Current', 'Both', 'Workstation Location', 'Broadcast Print', 'Physical Printer' (selected), and 'Default Desktop Printer'. To the right of these are three dropdown menus: the first is empty, the second contains 'Primary Label Printer', and the third contains '\\ccxapprt1\scm-dtm-3c709L'. Below these are three more dropdown menus: 'Copies' with value '1', 'Priority' with value 'Normal', and 'Target Database' with value 'Current Active'. At the bottom left is a checkbox 'Process report locally' which is unchecked. At the bottom are buttons for 'Print', 'Preview', 'Cancel', and 'Help'.

- 7) **Note:** Do **not** change any other settings within the screen.

8) The report selection screen reappears.



9) Click **Close**.

10) Retrieve labels from designated label printer.

### 3. REFERENCES:

CRIS User Manual, NIH, 2004.

## INSTRUCTION # 5118-9 Completing/Canceling CRIS Order

### 1. SCOPE:

CRIS orders that do not require resulting, must be either completed or cancelled in the system. Once a CPS order set has been verified and the process has been finished, CPS staff must return to Patient List Display summary to finalize the donor or assigned patient/recipient order.

### 2. PROCEDURE:

#### 2.1 Completing the (Processing) Order

NOTE: Component orders are completed in CRIS when orders are “finished” in Softbank. “Completing” order in CRIS consists of verifying “final” status in CRIS.

- 1) Select donor or assigned patient/recipient from **Patient List Display**.
- 2) With the donor or assigned patient/recipient selected, click **Order** tab.
- 3) Once order is complete, left click on appropriate order to highlight it.

LAB RESULTS TEST, NONAME - Sunrise Clinical Manager

File Edit View GoTo Actions Preferences Tools Help

LAB RESULTS TEST, NONAME 10-00-00-7 / 01010101010 69y Female

OP-OP2E-CC Unreviewed

Patient List Orders Results Documents Observations Patient Info Summary

Chart: This Chart

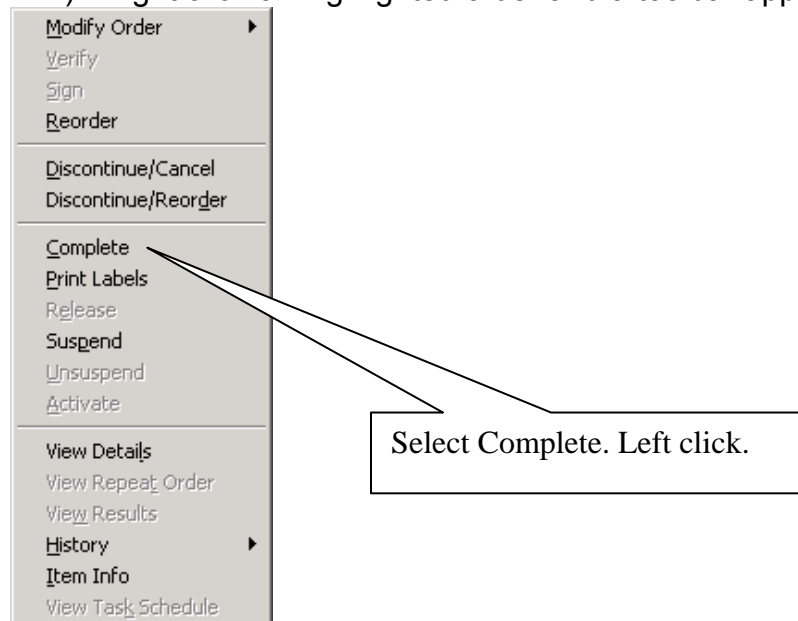
Date Range: Since 9 / 1 / 2004 To: / / Status: All Order 9

Can adjust this date range to limit or expand orders available for viewing

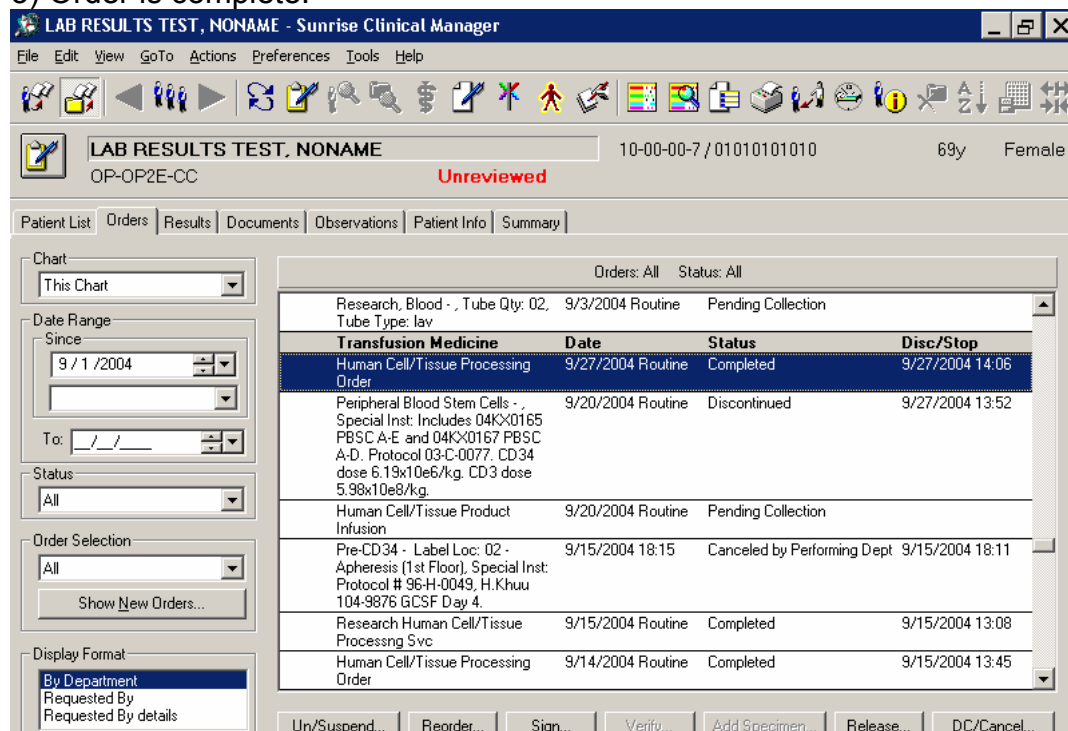
Transfusion Medicine	Date	Status	Disc/Stop
Human Cell/Tissue Processing Order	9/27/2004 Routine	Pending Collection	
Peripheral Blood Stem Cells - , Special Inst: Includes 04KX0165 PBSC A-E and 04KX0167 PBSC A-D. Protocol 03-C-0077. CD34 dose 6.19x10e6/kg. CD3 dose 5.96x10e8/kg.	9/20/2004 Routine	Discontinued	9/27/2004 13:52
Human Cell/Tissue Product Infusion	9/20/2004 Routine	Pending Collection	
Pre-CD34 - Label Loc: 02 - Apheresis (1st Floor), Special Inst: Protocol # 96-H-0049, H.Khuu 104-9876 GCSF Day 4.	9/15/2004 18:15	Canceled by Performing Dept	9/15/2004 18:11
Research Human Cell/Tissue Processing Svc	9/15/2004 Routine	Completed	9/15/2004 13:08
Human Cell/Tissue Processing Order	9/14/2004 Routine	Completed	9/15/2004 13:45
Peripheral Blood Stem Cells - , Special Inst: 04KX0163 PBSC B.	9/13/2004 Routine	Pending Collection	

Un/Suspend... Reorder... Sign... Verify... Add Specimen... Release... DC/Cancel...

4) Right click on highlighted order and a toolbar appears.



5) Order is complete.



## 2.2 Canceling an Order

- 1) Select donor or assigned patient/recipient from **Patient List Display**.
- 2) With donor or assigned patient/recipient selected, click **Order** tab
- 3) Once order is completed, left click on appropriate order to highlight it.

**LAB RESULTS TEST, NONAME - Sunrise Clinical Manager**

File Edit View GoTo Actions Preferences Tools Help

LAB RESULTS TEST, NONAME 10-00-00-7 / 01010101010 69y Female  
 OP-OP2E-CC Unreviewed

Patient List Orders Results Documents Observations Patient Info Summary

Chart: This Chart

Date Range: Since 9 / 1 / 2004 To: / /

Status: All Order: All

Display Format: By Department Requested By Requested By details

Orders: All Status: All

Transfusion Medicine	Date	Status	Disc/Stop
Peripheral Blood Stem Cells - , Special Inst: Includes 04KX0165 PBSC A-E and 04KX0167 PBSC A-D. Protocol 03-C-0077. CD34 dose 6.19x10e6/kg. CD3 dose 5.98x10e8/kg.	9/20/2004 Routine	Pending Collection	
Human Cell/Tissue Product Infusion	9/20/2004 Routine	Pending Collection	
Pre-CD34 - Label Loc: 02 - Apheresis (1st Floor). Special Inst: Protocol # 96-H-0049, H.Khuu 104-9876 GCSF Day 4.	9/15/2004 18:15	Canceled by Performing Dept	9/15/2004 18:11
Research Human Cell/Tissue Processing Svc	9/15/2004 Routine	Completed	9/15/2004 13:08
Human Cell/Tissue Processing Order	9/14/2004 Routine	Completed	9/15/2004 13:45
Peripheral Blood Stem Cells - , Special Inst: 04KX0183 PBSC B. Protocol 04-H-0112. CD34 dose 5.32x10e6/kg.	9/13/2004 Routine	Pending Collection	

Un/Suspend... Reorder... Sign... Verify... Add Specimen... Release... DC/Cancel...

Ready Khuu, Hanh M (MD)

4) Right click on highlighted order and a toolbar appears.

Modify Order  
 Verify  
 Sign  
 Reorder  
 Discontinue/Cancel  
 Discontinue/Reorder  
 Complete  
 Print Labels  
 Release  
 Suspend  
 Unsuspend  
 Activate  
 View Details  
 View Repeat Order  
 View Results  
 History  
 Item Info  
 View Task Schedule

Select Discontinue/Cancel and Left click

[illegible]

**DC/Cancel**

By... ☐ Me ☒ Other

Reason: Physician DC Order

When... ☒ Now

☐ Apply to

- Exam Replaced
- IV Present
- Late Cancel
- Physician DC Order**
- No Show
- Not on Clinical Pathway
- Clarification of order
- Entered on Wrong Patient
- Patient Discharged
- Patient Doctor Canceled
- Patient Expired



**LAB RESULTS TEST, NONAME - Sunrise Clinical Manager**

File Edit View GoTo Actions Preferences Tools Help

**LAB RESULTS TEST, NONAME** 10-00-00-7 / 01010101010 69y Female  
 OP-OP2E-CC **Unreviewed**

Patient List Orders Results Documents Observations Patient Info Summary

Chart: This Chart

Date Range: Since 9 / 1 / 2004 To: / / Status: All

Order Selection: All Show New Orders...

Display Format: By Department Requested By Requested By details

Orders: All	Status: All
Peripheral Blood Stem Cells - Special Inst: Includes 04KX0165 PBSC A-E and 04KX0167 PBSC A-D. Protocol 03-C-0077. CD34 dose 6.19x10e6/kg. CD3 dose 5.96x10e8/kg.	9/20/2004 Routine Discontinued 9/27/2004 13:52
Human Cell/Tissue Product Infusion	9/20/2004 Routine Pending Collection
Pre-CD 34 - Label Loc: 02 - Apheresis (1st Floor), Special Inst: Protocol # 96-H-0049, H.Khuu 104-9876 GCSF Day 4.	9/15/2004 18:15 Canceled by Performing Dept 9/15/2004 18:11
Research Human Cell/Tissue Processing Svc	9/15/2004 Routine Completed 9/15/2004 13:08
Human Cell/Tissue Processing Order	9/14/2004 Routine Completed 9/15/2004 13:45
Peripheral Blood Stem Cells - Special Inst: 04KX0183 PBSC B. Protocol 04-H-0112. CD34 dose 5.32x10e6/kg.	9/13/2004 Routine Pending Collection
Human Cell/Tissue Product	9/13/2004 Routine Discontinued 9/14/2004 20:58

Un/Suspend... Reorder... Sign... Verify... Add Specimen... Release... DC/Cancel...

### 3. REFERENCES:

CRIS Practice Exercise Workbook, Non-Prescriber Order Entry, NIH, 2004.